Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

End stage renal disease (ESRD): percentage of adult dialysis patients with a 3-month rolling average of total uncorrected calcium (serum or plasma) greater than 10.2 mg/dL (hypercalcemia).

Source(s)

Centers for Medicare & Medicaid Services (CMS). Measure information form: proportion of patients with hypercalcemia. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 6 p.

Centers for Medicare & Medicaid Services (CMS). Measure justification form: proportion of patients with hypercalcemia. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 50 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Outcome

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of adult dialysis patients with a 3-month rolling average of total uncorrected calcium (serum or plasma) greater than 10.2 mg/dL (hypercalcemia).

Rationale

The hypercalcemia measure was developed in 2010 based on the recommendations of a clinical technical expert panel 's (TEP's) consideration of the multiple large, risk-adjusted observational studies demonstrating a consistent relationship between presence of hypercalcemia and patient mortality. TEP members felt that while small, the population of patients with hypercalcemia was at increased risk of cardiovascular events and therefore the condition needs to be identified and appropriately treated. The

TEP agreed that therapy should be focused on preventing the development of a sustained serum calcium greater than 10.2 mg/dL.

The measure was re-evaluated by a second clinical TEP in 2013. The 2013 TEP identified additional observational studies supporting the measure and affirmed their agreement with the measure's focus as a safety measure, emphasizing avoidance of hypercalcemia to prevent adverse clinical consequences. Given both the 2010 TEP and 2013 TEP recommendations, and the additional evidence cited in the current National Quality Forum (NQF) submission, the developer maintains its importance as a clinical intermediate outcome and patient safety measure.

The developer acknowledges the lack of interventional trials supporting a specific threshold. However, the number of large, risk-adjusted observational studies with consistent direction of association between hypercalcemia and mortality cannot be ignored. Given this, several committee reviewers agreed with the prior TEP's opinions that the measure represented an appropriate safety-net.

As an additional concern, the Protecting Access to Medicare Act of 2014 mandated the implementation of conditions treated through oral-only medications in the End-stage Renal Disease (ESRD) Quality Incentive Program (QIP) as a safety measure against over-use of oral-only medications following changes to the ESRD Prospective Payment System (PPS) Bundle payment. The developer believes Congress recognized the need for more safety measures in the ESRD program, particularly in the area of drug overuse, following similar concerns for the use of erythropoiesis-stimulating agents (ESAs) in treating anemia in the same population. This hypercalcemia measure is the only measure of which the developer is aware that meets these requirements and the NQF criteria. Other relevant measures have been presented to NQF in the past, but have not received endorsement due to a lack of evidence.

Evidence for Rationale

Centers for Medicare & Medicaid Services (CMS). Measure justification form: proportion of patients with hypercalcemia. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 50 p.

Primary Health Components

End stage renal disease (ERSD); hypercalcemia; hemodialysis; peritoneal dialysis; serum or plasma calcium

Denominator Description

Number of patient-months among adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had end-stage renal disease (ESRD) for greater than 90 days (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Number of patient-months in the denominator with 3-month rolling average of total uncorrected serum (or plasma) calcium greater than 10.2 mg/dL (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A systematic review of the clinical research literature (e.g., Cochrane Review)

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

High Priority

In 2011, total Medicare costs for the end-stage renal disease (ESRD) program were $34.3 billion, a 5.4% increase from 2010 (United States Renal Data System, 2013). Abnormalities in serum levels of calcium and phosphorus, which are markers of mineral and bone disorder, are common among ESRD patients. Numerous studies have demonstrated the association of prolonged calcium and phosphorus dysregulation on patient morbidity and mortality (Kidney Disease: Improving Global Outcomes [KDIGO] CKD-MBD Work Group, 2009; National Kidney Foundation [NKF], 2003).

In March 2010, the clinical technical expert panel (C-TEP) recommended that a clinical performance measure (CPM) for the upper limit of total serum calcium be calculated as the proportion of patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL. This recommendation is consistent with the value indicated by a TEP held in 2006 and with the 2003 KDOQI guidelines (NKF, 2003). Since 10.2 mg/dl is the considered the upper limit of the normal range in the majority of clinical laboratories, this CPM is also consistent with the recently published KDIGO guidelines (KDIGO CKD-MBD Work Group, 2009).

Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality (Block et al., 2004; Young et al., 2005; Kalantar-Zadeh et al., 2006; Kimata et al., 2007; Tentori et al., 2008). Clinical data demonstrate the association of increased serum calcium with vascular (Chertow et al., 2004; Dhingra et al., 2007) and valvular calcifications (Wang et al., 2009). The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification (Ketteler, Schlieper, & Floege, 2006; Giachelli, 2004; Yang, Curinga, & Giachelli, 2004). Although there are no interventional studies demonstrating the benefit of correcting hypercalcemia, there was unanimous agreement among the C-TEP members that calcium concentrations greater than 10.2 mg/dL place the patient at increased risk of poor outcomes. Current guidelines indicate that clinical decision should be based on trends rather than single laboratory values (KDIGO CKD-MBD Work Group, 2009). Therefore, it was unanimously agreed to use a three-month rolling average for reporting.

Evidence for Additional Information Supporting Need for the Measure

Block GA, Klassen PS, Lazarus JM, Ofsthun N, Lowrie EG, Chertow GM. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. J Am Soc Nephrol. 2004 Aug;15(8):2208-18. [37 references] PubMed

Centers for Medicare & Medicaid Services (CMS). Measure justification form: proportion of patients with hypercalcemia. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 50 p.

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Med. 2007 May 14;167(9):879-85. PubMed

Giachelli CM. Vascular calcification mechanisms. J Am Soc Nephrol. 2004 Dec;15(12):2959-64. [60 references] PubMed

Kalantar-Zadeh K, Kuwae N, Regidor DL, Kovesdy CP, Kilpatrick RD, Shinaberger CS, McAllister CJ, Budoff MJ, Salusky IB, Kopple JD. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. Kidney Int. 2006 Aug;70(4):771-80. [45 references] PubMed

Ketteler M, Schlieper G, Floege J. Calcification and cardiovascular health: new insights into an old phenomenon. Hypertension. 2006 Jun;47(6):1027-34. [75 references] PubMed

Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2009 Aug;(113):S1-130. [477 references] PubMed

Kimata N, Albert JM, Akiba T, Yamazaki S, Kawaguchi T, Kawaguchi Y, Fukuhara S, Akizawa T, Saito A, Asano Y, Kurokawa K, Pisoni RL, Port FK. Association of mineral metabolism factors with all-cause and cardiovascular mortality in hemodialysis patients: the Japan dialysis outcomes and practice patterns study. Hemodial Int. 2007 Jul;11(3):340-8. PubMed

National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis. 2003 Oct;42(4 Suppl 3):S1-201. [664 references] PubMed

Tentori F, Blayney MJ, Albert JM, Gillespie BW, Kerr PG, Bommer J, Young EW, Akizawa T, Akiba T, Pisoni RL, Robinson BM, Port FK. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis. 2008 Sep;52(3):519-30. PubMed

United States Renal Data System. 2013 USRDS annual data report: epidemiology of kidney disease in the United States. Bethesda (MD): National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2013. various p.

Wang AY, Lam CW, Wang M, Chan IH, Lui SF, Sanderson JE. Is valvular calcification a part of the missing link between residual kidney function and cardiac hypertrophy in peritoneal dialysis patients?. Clin J Am Soc Nephrol. 2009 Oct;4(10):1629-36. [34 references] PubMed

Yang H, Curinga G, Giachelli CM. Elevated extracellular calcium levels induce smooth muscle cell matrix mineralization in vitro. Kidney Int. 2004 Dec;66(6):2293-9. [26 references] PubMed

Young EW, Albert JM, Satayathum S, Goodkin DA, Pisoni RL, Akiba T, Akizawa T, Kurokawa K, Bommer J, Piera L, Port FK. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. Kidney Int. 2005 Mar;67(3):1179-87. [18 references] PubMed

Extent of Measure Testing

Reliability Testing

Method of Reliability Testing

The developer used January 2013 – December 2013 CROWNWeb data to calculate facility level monthly and annual performance scores. 5,880 facilities that had at least 11 eligible patients were included in the testing. This included a total of 482,444 patients.

The developer assessed reliability by calculating facility-level Pearson correlation coefficients between the

current performance month and the preceding month for reporting months during January 2013 – December 2013. In addition, the developer calculated inter-unit reliability (IUR) for each reporting month and the overall 12 months. The monthly based measure was a simple average across individuals in the facility. The National Quality Forum (NQF)-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The IUR measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based measure, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA.

Statistical Results from Reliability Testing
The Pearson correlation coefficients of each pair of the current and the preceding month ranged from 0.78 to 0.84. All were statistically significant (p less than 0.0001), indicating this measure is reliable over time.

The monthly IURs ranged from 0.61 to 0.66, which indicates that more than half of the variation in the monthly based measure can be attributed to the between facility differences and less than half to within facility variation. The annual IUR across the 12 reporting months was 0.86, which indicates that 86% of the variation in the yearly based measure can be attributed to the between facility variation.

Interpretation
The IURs provide evidence of reliability in that most of the variation can be attributed to the between facility variation. The monthly and overall IURs suggest this measure is reliable. However, since the distribution of performance scores is skewed, the IUR value should be interpreted with some caution. The moderate to strong statistically significant results of the Pearson correlations indicates this measure is reliable over time.

Validity Testing

Method of Validity Testing
The developer used January 2013 – December 2013 CROWNWeb data to calculate facility level monthly and annual performance scores. 5,880 facilities that had at least 11 eligible patients were included in the testing.

This included a total of 482,444 patients.

The developer assessed validity using Poisson regression models to identify the predictive strength of facility level performance scores for the measure, on mortality, using the 2013 standardized mortality ratio (SMR).

In 2010, the measure was unanimously ratified by the clinical technical expert panel (TEP) as a valid measure.

Statistical Results from Validity Testing
Poisson regression modeling was used to assess the predictive strength of facility level performance scores for hypercalcemia on mortality, using the 2013 NQF endorsed SMR. The results suggest the measure performance scores were predictive of mortality as measured by the SMR. For instance, the facility-level relative risk of mortality for a 10% increase in percent of patients with hypercalcemia, is 1.07 (p less than 0.0001).

Interpretation
The results of the Poisson regression suggest that facilities with a higher percentage of patient-months with hypercalcemia experience a higher standardized mortality rate relative to facilities with a lower percentage of patients with hypercalcemia. The direction of the relationship is as expected.

Refer to the original measure documentation for additional information.

Evidence for Extent of Measure Testing

Centers for Medicare & Medicaid Services (CMS). Measure justification form: proportion of patients with hypercalcemia. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 50 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory Procedure/Imaging Center

Hospital Outpatient

Managed Care Plans

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Single Health Care Delivery or Public Health Organizations

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health

Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

The measurement period

Denominator Sampling Frame

Enrollees or beneficiaries

Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

Number of patient-months among adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had end-stage renal disease (ESRD) for greater than 90 days.

Note: Refer to the original measure documentation for additional denominator details and calculation algorithm/measure logic.

Exclusions
Exclusions that are implicit in the denominator definition include:

- All patients who have not been in the facility the entire reporting month (transient patients)
- Patients who have had ESRD for less than 91 days

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions
Number of patient-months in the denominator with 3-month rolling average of total uncorrected serum (or plasma) calcium greater than 10.2 mg/dL

Note: If there are multiple calcium measurements during the month, the last value will be used for the calculation. Calcium measurements can be based on either serum or plasma calcium.

Exclusions
Unspecified

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Physiologic Health State (Intermediate Outcome)

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a lower score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Proportion of patients with hypercalcemia.

Measure Collection Name

End Stage Renal Disease (ESRD) Quality Measures

Submitter

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

Developer

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

Funding Source(s)

Centers for Medicare & Medicaid Services (CMS)

Composition of the Group that Developed the Measure

The University of Michigan Kidney and Epidemiology Cost Center (UM-KECC), develops, maintains, and updates the End Stage Renal Disease (ESRD) Quality Measures for the Centers for Medicare and Medicaid Services (CMS), under the Quality Measure Development and Maintenance contract with CMS. In addition, UM-KECC works with CMS's Measures Management System (MMS) in the development, evaluation, and reporting of the current ESRD Quality Measures.

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Endorser

National Quality Forum - None

NQF Number

not defined yet

Date of Endorsement

2015 Oct 2

Measure Initiative(s)

Dialysis Facility Compare (DFC)

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Sep

Measure Maintenance

Annually

Date of Next Anticipated Revision

Unspecified

Measure Status

Please note: This measure has been updated. The National Quality Measures Clearinghouse is working to update this summary.

Measure Availability

Source available from the Dialysis Data Web site .

For more information, refer to the Dialysis Data Web site or contact Casey Parrotte at the Kidney Epidemiology and Cost Center, The University of Michigan, 1415 Washington Heights, Suite 3645 SPHI, Ann Arbor, MI 48109-2029; Phone: 734-763-6611; Fax: 734-763-4004; Email: parrotte@med.umich.edu.

NQMC Status

This NQMC summary was completed by ECRI Institute on December 5, 2014. The information was verified by the measure developer on February 6, 2015.

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Copyright Statement

Production

Source(s)

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